

**AMENDMENT OF NIAID SOLICITATION
RFP NIH-NIAID-DAIDS-08-33
“NIAID HIV/AIDS Scientific and Operations Support”**

Solicitation Number: RFP-NIH-NIAID-DAIDS-08-33
Amendment Number: One (1)
Amendment Issue Date: Tuesday, June 5, 2007

Proposal Due Date: (Unchanged) **Tuesday, June 8, 2007 at 4:00 PM, Local Time**

Issued By: Anita Hughes
Contract Specialist
NIAID, NIH, DHHS
Office of Acquisitions, DEA
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

Point of Contact: Anita Hughes
E-mail: anhughes@niaid.nih.gov

This amendment provides questions and answers regarding the RFP. The proposal due date and time are unchanged. Offerors must acknowledge receipt of this amendment by identifying this amendment number and date of the amendment on each copy of the offer submitted. Failure to receive your acknowledgement may result in the rejection of your offer. Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

Questions and Answers

- 1) Reference Part I, Contract Schedule, ARTICLE G.4., Indirect Cost Rates. We understand that the Contract Schedule included in Part I of the RFP "is not an exact representation of the proposed contract document." However, ARTICLE G.4. identifies a Contracting Officer representative responsible for "negotiating provisional and/or final indirect cost rates" while at the same time incorporating "these rates" by reference without further action of the Contracting Officer. Please explain.

Answer: This applies to commercial/for profit contractors only. It is NIH policy that commercial/for profit contractors negotiate overhead rates with the Division of Financial Advisory Services to whom Contracting Officer authority has been delegated for this purpose. Once rates are negotiated, they are automatically incorporated into the contract.

2) Reference Part IV, Section L.1.f., Level of Effort. The referenced sections lists the labor categories associated with the 77 FTEs.

- a. Will NIAID consider providing the job descriptions associated with these labor categories and the performance requirements for these positions?

Answer: No, NIAID will not be providing job descriptions for these labor categories. Job descriptions are the responsibility of the employer and not the Government. We have provided the Statement of Work which includes the performance requirements.

- b. Also, it is noted that the Project Director position is estimated at 20% FTE. As a 20% FTE, presumably, the Project Director would be working on other Offeror projects with the other 80% of his or her time. Please explain how Offerors might reconcile this fact with the organizational separation required by the Conflict of Interest Mitigation, Non-Disclosure and Confidentiality requirements. Having the Project Director as anything less than 100% dedicated to the contract has the potential to impact the possible Organizational Conflicts of Interest that may arise.

Answer: As stated in the RFP, "The Government's requirement for the work set forth in the Statement of Work of this solicitation is 77 full time equivalents (FTE). It is estimated that the FTE are constituted as specified below and will be expended approximately as follows:" It is up to the offeror to estimate how the level of effort will be expended. The labor mix and categories of labor are left up to the offeror to propose as they deem appropriate to fulfill the requirements of the contract. If you believe that the Project Director should be 100% on this contract and feel you can justify it, you may propose this.

3) Reference Part IV, Section L.2.a.(11) Institutional Responsibility Regarding Conflicting Interests of Investigators and Institutional Management of Conflicting Interest. The referenced sections detail "Institutional" requirements relating to conflicting interests of investigators. Some of the terminology used in these sections is unclear in the context of this RFP, particularly since "investigator" is not one of the 77 labor categories identified in Section L.1.f. Please describe how the Section L.2.a.(11) provisions apply to Offerors.

Answer: This language is routinely included in NIH solicitations for research and development contracts. The proposed acquisition is considered to be in support of research and development so this language was included in the solicitation. It addresses the need for a research organizations to have in place established procedures to deal with research investigators who are carrying out research that might result in a conflict of interest (e.g., a clinical trial is being carried out using a

drug where the research investigator has stock in the company that manufactures the drug).

- 4) Reference Attachment 7, Section 6, Conflict of Interest Mitigation, Non-Disclosure and Confidentiality, III.C., requires Offerors to include in their technical proposal a "clear discussion of how the Contractor would preclude a perception of impaired objectivity by prohibiting transfer of personnel performed under **this contract** to work on or develop proposal(s) for funding for activities in which they had access to privileged information." *[Emphasis added]* III.D. requires Offerors to include in their technical proposal a "clear discussion of how the Contractor would counter an assertion that there would be unfair access to information by prohibiting transfer of personnel perform the **existing contract to the division** planned to support **the new proposed effort** (precluding transfer of information)." *[Emphasis added]* III.F. requires Offerors to include in their technical proposal a "clear explanation of how the Contractor intends to organize itself such that all new work under the proposed new contract effort will be performed by a division that has no contract responsibilities or management of the existing contract that is causing the COI (to ensure objectivity)." *[Emphasis added]* III.G. requires Offerors to include in their technical proposal a "clear explanation of steps it will take to ensure any personnel hired under this contract, including sub-contractors and consultants adhere to the approved conflict of interest mitigation and non-disclosure plans." *[Emphasis added]* The use of the emphasized terminology above is unclear.

- a. Do the terms "this contract" (as used in III.C. and III.G.) and "the existing contract" (as used in III.D. and III.F.) both refer to the contract that will result from RFP NIH-NIAID-DAIDS-08-33? To what effort(s) do the terms "new proposed effort" as used in III.D.) and "proposed new contract effort" (as used in III.F.) refer? Please elaborate sufficiently to clarify the terminology used.

Answer: Yes, "this contract" and "the existing contract" refer to the contract that will result from the RFP. The terms "new proposed effort" and "proposed new contract effort" refer to any new proposed effort that the NIAID may solicit for separately. In other words, "the new proposed effort" refers to a hypothetical solicitation used to describe a scenario to which NIAID is requesting the offeror under RFP 08-33 provide a description of how the offeror will operate. The "new contract effort" is the hypothetical contract that would result from the hypothetical solicitation. NIAID is asking the offeror to describe, if NIAID awarded the contract to the offeror, how the offeror would prevent itself from obtaining competitive advantage in the hypothetical situation by virtue of its participation in developing the hypothetical solicitation. The simplest and cleanest solution is for the offeror to not compete.

- b. The conflict of interest mitigation, non-disclosure and confidentiality requirements detailed in Section 6 appear to contemplate at least two separate

and distinct Offeror "divisions" performing work relating to this RFP, one that would perform "all new work under the proposed new contract" and one performing work relating to "the existing contract." Please clarify the organizational requirements relating to this RFP, in particular the requirement in III.F. that the Contractor "organize itself such that all new work under the proposed new contract effort... be performed by a division that has no contract responsibilities or management of the existing contract that is causing the COI."

Answer: The RFP does not state that two separate offeror divisions will perform this work. We are simply asking you to clarify organization requirements. We are not specifying how you should organize or structure your company. However, you need to provide a plausible and workable means of avoiding the conflicts.

- 5) Reference Pat IV, Section L.2.b.(6), Information Security. This section requires Offerors to address the Information Security requirements of the Statement of Work in a separate section of the Technical Proposal and indicates that the "Statement of Work requires the successful offeror to 1) develop, 2) have the ability to access, or 3) host and/or maintain Federal Information system(s)." However, it is unclear, for the systems identified below, whether the Contractor will be required to 1) develop, 2) have the ability to access, or 3) host and/or maintain these systems. Thus, please explain the level of support that will be required for the following proposed system implementations identified in the Statement of Work:
- a. Clinical Research Document Tracking (Attachment 3, page 7).
 - b. Portfolio Tracking, Analysis and Monitoring (Attachment 3, page 9). Data Management Systems and Data Quality Assurance (Attachment 3, page 9).

Answer: For all of the above, the Contractor will be required to have the ability to access, host, and maintain existing federal information technology systems. At this point in time, we do not anticipate any systems development.

- 6) Reference Attachment 3, Statement of Work, 1.F., Clinical Research Document Tracking. Please indicate whether there is a specific system being considered to serve as the Clinical Research Document Tracking Systems, and if there is, please identify the system. Please also indicate the offices and sites the system will support.

Answer: There is no specific system being considered. We would prefer off the shelf software. The systems will support the extramural offices of NIAID in Bethesda, Maryland.

- 7) Reference Attachment 3, Statement of Work, 2.A., Portfolio Tracking, Analysis and Monitoring. Please identify any software packages being considered to support the requirements described in this section. Please also indicate what organizations specifically (indicating both NIAID activities and non-NIAID activities) will be using

the Portfolio Tracking, Analysis and Monitoring system. Please also indicate the offices and sites the system will support.

Answer: There is no specific system being considered. We would prefer off the shelf software. The systems will support the extramural offices of NIAID in Bethesda, Maryland. Non-NIAID activities will not be using this system.

- 8) Reference Part IV, Section L.2.b.(1)c)(4), Resumes and Attachment 7, Additional Technical Proposal Instructions, Section 4, Qualifications and Availability of Personnel. Section L.2.b.(1)c)(4) requires resumes of all key personnel while the reference section in Attachment 7 appears to contemplate Offerors including the resumes/CVs of all proposed personnel. Please clarify the proposed instructions relative to the resume/CV requirement. If Offerors provide one-page resumes for all personnel, that would take up 77 pages out of the 200 allowed for the Technical Proposal.

Answer: You may include the resumes as Appendices which would not count towards the 200 page limit.

- 9) Reference Part IV, Section L.2.c.(10)e), Pertinent Grants. The referenced section requires Offerors to "list grants supported by the Government that involved similar or related work that that called for in this RFP." Please indicate whether Offerors should list all pertinent grants, all pertinent current grants, or all pertinent grants issued in the past 3 years. In other words, please indicate any limitations on the number of grants to be listed. Also, should pertinent cooperative agreements be listed as well?

Answer: There are no limitations on the number of grants to be listed. However, the grants should be pertinent or similar to the work that will be done under this contract. Yes, the NIH considers cooperative agreements to be a type of grant.

- 10) Reference Part I, Contract Schedule, ARTICLE F.3., Level of Effort. Paragraph a. of the referenced Article includes an option for the Contracting Officer to "[INCLUDE/EXCLUDE]" vacation, holiday, and sick leave in the definition of direct labor hours. Please clarify whether vacation, holiday, and sick leave are excluded from the labor definition as this will have a direct impact on the determination whether the Contractor has satisfied the level of effort requirement and by extension the determination of fee.

Answer: This information is completed at the time of contract award. It is Contractor dependent so we could not have provided this information in the RFP. That is why in the solicitation we defined the level of effort in terms of full time equivalents rather than direct labor hours.

11) Will the RFP be extended?

Answer: No. If we extend the due date, a new contract will not be awarded within the timeframe that is required.